Exhibit 66

FAQs: Organic Impurities

USP provides answers to Frequently Asked Questions (FAQs) as a service to stakeholders and others who are seeking information regarding USP's organization, standards, standards-setting process, and other activities. These are provided for informational purposes only and should not be construed as an official interpretation of USP text or be relied upon to demonstrate compliance with USP standards or requirements. USP does not endorse any specific brand or product. For questions not answered here, USP provides multiple routes of support by which the public may seek additional information. Questions on specific standards should be directed to the appropriate contact listed on the Scientific Support (https://www.usp.org/help/scientific-support) page.

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- What are the acceptance criteria for the Relative Retention Time (RRT)?
- If my chromatogram contains a peak with the same RRT as that of a specified impurity / specified degradation product, does this prove the impurity is present in my product?
- Where do the Organic Impurities tests, acceptance criteria, and the related impurity profiles in drug substance and drug product monographs come from?
- What does it mean to characterize the impurity profile of a product?

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As described in applicable guidance, which include, but are not limited to, FDA's Guidance for Industry, Q3A Impurities in New Drug Substances, June 2008, ICH, Revision 2; FDA's Guidance for Industry, Q3B(R2) Impurities in New Drug Products, August 2006, ICH, Revision 3; and *USP* General Chapter ‹1086› Impurities in Drug Substances and Drug Products, the characterization of a product's impurity profile refers to the process of establishing the impurities and degradation products (both actual and potential) that are most likely to arise during the synthesis, purification, and storage of a drug substance and additionally during the manufacturing and storage of a drug product. These impurities and degradation products may be identified, as is required when their content exceeds the applicable identification threshold established by the regulatory authority, but they may also include unidentified impurities and unidentified degradation products. Differing synthetic routes and the unique chemical environments of different drug product formulations mean that impurity profiles may differ for different manufacturers' products.

The methods used to characterize an impurity profile include, but are not limited to, a sound scientific appraisal of the chemical reactions involved in the synthesis of the drug substance and the impurities associated with raw materials, stability studies, forced degradation studies, and knowledge of degradation pathways. Analytical techniques capable of providing structural information may be employed to establish the identity of detected impurities, when appropriate. These techniques include, but are not limited to, ultraviolet (UV) spectroscopy, infrared (IR) spectroscopy, mass spectroscopy (MS), and nuclear magnetic resonance (NMR) spectroscopy. Chromatographic relative retention times (RRTs) provided in some USP Organic Impurities tests are not conclusive and, therefore, cannot be used as the sole means to establish the identity of an impurity.

- The *Acceptance criteria* for some drug products provide limits for *Total impurities* while others provide limits for *Total degradation products*. What is the difference?

- When can drug substance process impurities be excluded from a drug product's *Total degradation products* result?

- The Organic Impurities specifications for my FDA-approved product differ from those in the monograph. Should I request a revision of the public standard?

- Is it necessary to list every specified impurity from the monograph on my drug substance certificate of analysis (COA)?

- The *System suitability* section in some Organic Impurities (O.I.) tests includes a table with RRTs for specified impurities / specified degradation products as well as other compounds that are not specified. What is the purpose of this table? Are these impurities being controlled by the O.I. test, and if so, what are their related acceptance criteria and relative response factors (RRFs), if applicable?

- Where can I learn more about controlling organic impurities in drug substances and drug products?

Also of Interest

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200 years of helping to improve global health (https://www.usp.org/200-anniversary)

What is a USP Monograph (https://www.usp.org/about/public-policy/overview-of-monographs)